

REMARKS

Formal Matters

Claims 1-10 and 43-51 are pending after entry of the amendments set forth herein.

Claim 1 has been amended to specify that the flavin agent is present at a concentration that ranges from about 1 mM to about 15 mM. Support for this amendment may be found in the specification, e.g., at page 7, lines 3-8. Claim 7 has been amended to correct a minor informality. The amendments to these claims were made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim.

Claims 43-51 have been added as new. Support for these claims may be found in the specification and the originally filed claims, e.g., at page 6, line 8 to page 7, line 14.

New matter has been added by these amendments. Accordingly, Applicants respectfully request entry thereof.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

Objections and Rejections under 35 U.S.C. §112

The Applicants note that in a telephone interview held on June 4, 2004, the Examiner confirmed that the objections and rejections under 35 USC 112, ¶1 and ¶2 have been overcome.

Objections Rejections under 35 U.S.C. §102

Independent Claim 1, and the claims that depend therefrom, have been amended to specify that the flavin agent is present at a concentration that ranges from about 1 mM to about 25 mM. In a telephone interview held on June 4, 2004, it was agreed that none of the cited references (Ouyang et al. (EP1130111 A2), Nippon Chemiphar (Derwent 1985-070861), Steinbach et al., (US 4,724,204)) teach a flavin agent present at a concentration that ranges from about 1 mM to about 25 mM. Accordingly, the Applicants submit that Claim 1, and the claims that depend therefrom, are not anticipated by the cited references. Accordingly, the Applicant respectfully requests that the rejection of the claims under 35

USC 102 as anticipated by Ouyang et al., Nippon Chemiphar, Steinbach et al., and Geisler et al. be withdrawn.

Rejection under 35 U.S.C. §103 – Nippon and Geisler et al.

Claims 1-10 and 33-42 are rejected under 35 U.S.C. §103(a) as unpatentable in view of Nippon and Geisler et al. Claims 33-42 are cancelled. The Applicants respectfully traverse this rejection with respect to claims 1-10 and newly added claims 43-51.

As noted above, these claims specify a composition that includes a flavin agent present at a concentration that ranges from about 1 mM to about 25 mM. Nippon in view of Geisler et al. fails to teach or suggest a composition as claimed. Specifically, neither reference teaches or suggests a flavin agent at a concentration as claimed in the subject claims. Nippon employs a flavin agent as a coenzyme. As noted in the attached declaration, it is known in the art that the concentration of flavin agent employed as a coenzyme would be far less than the concentration of flavin agent claimed in the subject claims as the function of a coenzyme is merely to activate the enzyme and as such there is no reason to increase the concentration of a coenzyme above that minimal amount needed to activate the enzyme. Geisler et al. do not describe a flavin agent at all. Accordingly, there is not even any suggestion in the cited references or in any reference of record to include the claimed amounts of a flavin agent in the compositions of Nippon and/or Geisler et al.

Accordingly, for at least this reason, the Applicants respectfully submit that this rejection of the claims under 35 U.S.C. §103 be withdrawn.

Rejection under 35 U.S.C. §103 – Ouyang et al.

Claims 1-2, 4-10, 33 and 35-41 are rejected under 35 U.S.C. §103(a) as unpatentable in view of Ouyang et al. Claims 35-41 have been cancelled. The Applicants respectfully traverse this rejection with respect to claims 1-2, 4-10 and newly added claims 43-51.

As noted above, claim 1, and the claims that depend therefrom, specify a composition that includes a flavin agent present at a concentration that ranges from about 1 mM to about 25 mM. Ouyang et al. fail to teach or suggest a composition as claimed. Specifically, Ouyang et al. do not teach or

suggest a flavin agent at a concentration as claimed in the subject claims. Ouyang et al. employ a flavin agent as a coenzyme and as such does not render the instant claims unpatentable for reasons analogous to those described above. Accordingly, there is not even any suggestion in the cited reference or in any reference of record to include the claimed amounts of a flavin agent in the compositions of Ouyang et al.

Accordingly, for at least this reason, the Applicants respectfully submit that this rejection of the claims under 35 U.S.C. §103 be withdrawn.

Rejection under 35 U.S.C. §103 – Steinbach et al.

Claims 1, 2, 4, 6, 8, 33, 37 and 39 are rejected under 35 U.S.C. §103(a) as unpatentable in view of Steinbach et al. Claims 33, 37 and 39 have been cancelled. The Applicants respectfully traverse this rejection with respect to claims 1, 2, 4, 6, 8 and newly added claims 43-51.

As noted above, claim 1, and the claims that depend therefrom, specify a composition that includes a flavin agent present at a concentration that ranges from about 1 mM to about 25 mM. Steinbach et al. fail to teach or suggest a composition as claimed. Specifically, Steinbach et al. do not teach or suggest a flavin agent at a concentration as claimed in the subject claims. Steinbach et al. employ a flavin agent as a coenzyme and as such does not render the instant claims unpatentable for reasons analogous to those described above. Accordingly, there is not even any suggestion in the cited reference or in any reference of record to add include the claimed amounts of a flavin agent in the compositions of Steinbach et al.

Accordingly, for at least this reason, the Applicants respectfully submit that this rejection of the claims under 35 U.S.C. §103 be withdrawn.

Rejection under 35 U.S.C. §103 – Geisler et al.

Claims 34, 35, 37, and 39-41 are rejected under 35 U.S.C. §103(a) as unpatentable in view of Geisler et al. (US 4,613,569). These claims have been cancelled. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE-040.

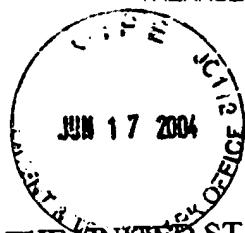
Respectfully submitted,
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Date: 4/17/01⁵⁰

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Ouyang, et al.

Serial No. 09/988,494

Filed: November 20, 2001

For: STABILIZED TETRAZOLIUM
PHENAZINE REAGENT
COMPOSITIONS AND METHODS
FOR USING THE SAME

Art Unit: 1615

Examiner: Davis, Ruth

Atty. Ref. LIFE-040

DECLARATION UNDER 37 C.F.R. 1.132

The Commissioner for Patents
Washington D.C. 20231

Dear Sir,

I, Tianmei Ouyang, am an inventor of the subject matter claimed in the patent application identified above (the "subject application"). Accordingly, I am qualified to speak on the level of one of skill in the art.

I hereby declare as follows:

1. I have read the Final Office Action dated October 17, 2003 and the Advisory Actions dated February 13, 2004 and April 16, 2004 for the above referenced application, as well as the references cited therein to support the rejections made by the Examiner.
2. The subject invention specifies a flavin agent at a concentration that ranges from about 1 mM to about 25 mM.
3. None of the cited references (US Patent No. 4,724,204 (the '204 patent) to Steinbach et al., EP 1 130 111 A2 (the '111 publication) to Ouyang et al., and Nippon Chemiphar (the Nippon reference)) teaches or suggests a flavin agent in the concentration range specified in the subject invention.

4. The '204 patent, the '111 publication and the Nippon reference all teach a flavin agent as a coenzyme.

5. There would be no motivation to include the claimed amounts of a flavin agent in any of the compositions of the cited references because each of these references describes the use of a flavin agent as a coenzyme and do not provide any other utility of the flavin agent.

6. It is well known in the art that the concentration of a coenzyme need only be that which is sufficient to activate an enzyme.

7. It is well known in the art that it is not necessary to increase the concentration of a coenzyme above which is needed to activate an enzyme.

8. It is well known in the art that the concentration required for a coenzyme to activate an enzyme is extremely low.

9. The stabilizing concentration of flavin agent employed in the subject application is far greater than which would be required if it were employed as a coenzyme.

10. Accordingly, none of the cited reference teaches, discloses or fairly suggests a tetrazolium dye/phenazine electron transfer agent composition having a flavin agent at a concentration that ranges from about 1 mM to about 25 mM.

I hereby declare that all statements made herein of my own knowledge and are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued therefrom.

Respectfully submitted,

Date: 6/16/04

TM
Tianmei Ouyang